:: 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Agency for Healthcare Research and Quality** 

Supplemental Evidence and Data Request on Strategies for Integrating Behavioral Health

and Primary Care

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Request for Supplemental Evidence and Data Submissions

**SUMMARY:** The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific

information submissions from the public. Scientific information is being solicited to inform our

review on Strategies for Integrating Behavioral Health and Primary Care, which is currently

being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to

published and unpublished pertinent scientific information will improve the quality of this

review.

**DATES:** Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF

PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** 

*E-mail submissions:* epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E77D

Rockville, MD 20857

FOR FURTHER INFORMATION CONTACT: Jenae Benns, Telephone: 301-427-1496 or

Email: epc@ahrq.hhs.gov.

**SUPPLEMENTARY INFORMATION:** The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Center (EPC) Program to complete a review of the evidence for Strategies for Integrating Behavioral Health and Primary Care. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on Strategies for Integrating Behavioral Health and Primary Care, including those that describe adverse events. The entire research protocol is available online at:

https://effectivehealthcare.ahrq.gov/products/strategies-integrating-behavioral-health/protocol This is to notify the public that the EPC Program would find the following information on Strategies for Integrating Behavioral Health and Primary Care helpful:

• A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.

- For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

## **Questions for the Systematic Review**

Question 1 (Scan). What approaches have been used to integrate behavioral health and primary care?

- a. How do these approaches vary by:
  - (i) patient characteristics (e.g., clinical focus/conditions/patient subgroups)
  - (ii) core components of the approach
  - (iii) practice/care delivery setting characteristics such as the policy environment, and geographic location.
  - (iv) resources and infrastructure required, such as staffing, payment models, financing, and technology
  - (v) mechanisms of care integration

Question 2 (Key). How effective are approaches to integrating behavioral health and primary care?

- a. Does effectiveness vary by:
  - (i) patient characteristics (e.g., clinical focus/conditions/patient subgroups)
  - (ii) core components of the approach
  - (iii) practice/care delivery setting characteristics, such as the policy environment, and geographic location.
  - (iv) resources and infrastructure required, such as staffing, financing, payment models, and technology
  - (v) mechanisms of care integration
- b. How do interactions among the components of integration approaches impact effectiveness and maintenance of the integration of behavioral health and primary care?

Question 3 (Contextual). What are the barriers to and facilitators of implementing and sustaining different approaches to integrating behavioral health and primary care?

- a. How do the barriers, facilitators, and other factors involved in the implementation of behavioral health and primary care interact to affect implementation and sustainability?
   Question 4 (Contextual). What reliable, valid, clinically meaningful, and/or patient-centered measures and metrics are available to monitor and evaluate integration approaches?
  - a. How is measurement integrated into clinical care and the ongoing monitoring and evaluation of integration?
  - b. Are the measures or metrics specific to characteristics; level of complexity; or the structure, process, or outcomes of care integration?
  - c. Are there models or standards for how frequently the effectiveness of approaches to integration should be reassessed?
  - d. What are the gaps in measurement and what are the implications for our current ability to measure and assess integration?

Question 5 (Contextual). How are care team member roles and their work flows defined in different approaches to integrating behavioral health and primary care?

a. What training interventions (e.g., mode and content, trainee credentials, dose and timing of training) are effective in facilitating integrated care team functioning?

Population, Interventions, Comparators, Outcomes, and Setting (PICOS)

PICOS	Inclusion	Exclusion
Population	<ul> <li>Children (aged 0-20 years) and adults (aged ≥21 years) with behavioral health needs</li> <li>Clinical focus/conditions including but not limited to patients with</li> <li>Mental illness or mental health conditions.</li> <li>Substance use disorders</li> <li>Stress-linked physical symptoms (e.g., insomnia, fatigue)</li> <li>Complex overlapping medical conditions and psychosocial risk factors</li> <li>Experiences of trauma, adverse experiences, or stressful life events</li> <li>Pregnant patients.</li> <li>Geriatric patients.</li> </ul>	No exclusions for age or condition.
Intervention	Different approaches to integrating behavioral health and primary care services, including program/model components and strategies to integrate care.  Examples of eligible programs/models for care integration include but are not limited to:  Collaborative Care Model Primary Care Behavioral Health Model Co-location models Models that use telehealth for integration The baseline requirement is that the practice design of the approach facilitates interaction among primary care and behavioral health providers in the provision of care. Ongoing collaboration and coordination of care are required; activities may include screening and diagnosis, acute and long-term interventions, and follow up and maintenance.	<ul> <li>Co-location without collaboration.</li> <li>Referral only (cold handoff)</li> <li>Warm handoff without plan for continued communication and coordination of care.</li> <li>Population level health promotion or prevention programs that are not individualized, integrated care (e.g. Silver Sneakers).</li> <li>Interventions for chronic medical conditions that do not include a significant, explicit behavioral health component.</li> </ul>
Comparator	<ul> <li>Care as usual (e.g., non-integrated behavioral health and primary care services) in a different group or time period</li> <li>Alternative care integration strategy or strategies</li> <li>No care.</li> </ul>	<ul> <li>No comparator for KQ 2 (descriptive studies; such as case studies)</li> <li>Comparators not applicable to other questions.</li> </ul>

PICOS	Inclusion	Exclusion
Outcomes	Outcomes of interest include but not limited to:	Simulated results or
	PATIENT LEVEL	responses to hypothetical
	Health outcomes:	scenarios or questions
	Morbidity	1
	Mortality	
	Improved symptoms	
	<ul> <li>Guideline concordant screening and diagnosis</li> </ul>	
	Remission/recovery	
	Adherence to treatment	
	Patient Reported Outcomes:	
	Health related quality of life	
	• Functional status (including social and adaptive functioning)	
	Satisfaction with care	
	Measures of care utilization:	
	<ul> <li>Avoidable emergency care or inpatient care for behavioral health crises</li> </ul>	
	Total health care utilization	
	Measures of access to care:	
	Patients receive routine care as soon as wanted	
	Patients receive acute care when needed	
	Average wait time for BH	
	Patients experiencing difficulties or delays in	
	obtaining BH care	
	Patients with mental health condition received	
	treatment	
	Patients with SUDs received treatment	
	CLINICIAN AND PRACTICE LEVEL	
	Clinician Outcomes	
	Clinician retention/turnover rates	
	Burnout	
	Professional satisfaction	
	Efficiency of clinician time use	
	Population/community/clinic panel health outcomes:	
	BH-related preventive care measures	
	BH screening services	
	Cost outcomes:	
	Cost per patient per year	
	Cost per service	
	Costs associated with care delays,	
	fragmentation, poor coordination, redundancy,	
	requested but not completed patient referrals	
	Implementation Outcomes	
	Adoption of intervention approaches	
	Fidelity	
	Systemic Change/Sustainment	
	HARMS	
	Missed diagnoses	
	Delays in care	

PICOS	Inclusion	Exclusion
	<ul><li>Overutilization of resources</li><li>Redundant or inappropriate care</li></ul>	
Setting	<ul> <li>Health systems/hospitals and community-based primary care practices in the United States (physical or virtual) or in countries with similar healthcare systems</li> <li>Non-healthcare settings providing outpatient BH/PC (school-based clinics, community centers, churches, shelters)</li> <li>Nursing homes, group homes and other long-term residential settings.</li> </ul>	<ul> <li>Hospitals</li> <li>Prehospital/EMS/crisis care</li> <li>Prisons</li> <li>Countries with healthcare systems that do not provide information relevant to the U.S.</li> </ul>
Study Designs	<ul> <li>Experimental and observational studies that describe and evaluate integration approach</li> <li>For Scan Question 1 and Contextual Questions 3 and 5: Survey and Qualitative Studies</li> <li>For Contextual Question 4: Psychometric Studies</li> <li>Systematic reviews that directly address one of the review questions.</li> </ul>	<ul> <li>Articles that do not include any data.</li> <li>Proposals for approaches that have not been implemented</li> <li>Descriptions of approaches that have not been evaluated (for KQ2)</li> <li>Articles reporting simulation or speculation.</li> </ul>

Abbreviations: BH=behavioral health; EMS=emergency medical services; KQ=key question; PC=primary care

Dated: October 17, 2022.

## Marquita Cullom,

Associate Director.

[FR Doc. 2022-22843 Filed: 10/20/2022 8:45 am; Publication Date: 10/21/2022]